Massachusetts Department of Public Health
Division of Epidemiology and Immunization

Provisional Recommendations for the Use of Quadrivalent (types 6, 11, 16, 18) Human Papillomavirus (HPV) Vaccine

The recommendations outlined below are based on the Advisory Committee on Immunization Practices' (ACIP) provisional recommendations for use of HPV vaccine and several other references. When the final ACIP recommendations are published they will be accessible on the ACIP website http://www.cdc.gov/nip/ACIP/default.htm.

Provisional recommendations for use of quadrivalent HPV vaccine

- Routine vaccination with 3 doses of quadrivalent HPV vaccine is recommended for females 11-12 years of age. The vaccination series can be started in females as young as 9 years of age.
- Catch-up vaccination is recommended for females 13-26 years of age who have not been vaccinated previously or who have not completed the full vaccine series. Ideally, vaccine should be administered before potential exposure to HPV through sexual contact.
- Each dose of quadrivalent HPV vaccine is 0.5 mL, administered intramuscularly.
- Quadrivalent HPV vaccine is administered in a 3 dose schedule. The 2nd and 3rd doses should be administered 2 and 6 months after the first dose.
- Quadrivalent HPV vaccine can be administered at the same visit when other age appropriate vaccines are provided, such as Tdap, Td and MCV4.

HPV Vaccine Schedule

Dose	Schedule	Minimum Age/Interval[1,2,3]
1st Dose	0 mos	9 years
2nd Dose	2 mos (2 mos after 1st)	4 weeks
3rd Dose	6 mos (6 mos after 1st)	12 weeks

[1] There are no maximum intervals.
[2] If the schedule is interrupted, the vaccine series does not need to be repeated.
[3] The vaccine is licensed for a minimum age of 9 years and a maximum age of 26 years.

Special situations

- Quadrivalent HPV vaccine can be given to females who have an equivocal or abnormal Pap test, a positive Hybrid Capture II® high risk test, or genital warts.

  Vaccine recipients should be advised that there is no data to indicate that the vaccine has any therapeutic effect on existing Pap test abnormalities, HPV infection or genital warts. Vaccination of these females would provide protection against infection with vaccine HPV types not already acquired.
- Lactating women can receive quadrivalent HPV vaccine.
- Females who are immunocompromised either from disease or medication can receive quadrivalent HPV vaccine. However the immune response to vaccination and vaccine effectiveness might be less than in females who are immunocompetent.

Pregnancy

- Quadrivalent HPV vaccine is not recommended for use in pregnancy.
- The vaccine has not been associated causally with adverse outcomes of pregnancy or adverse events to the developing fetus. However, data on vaccination during pregnancy are limited. Any exposure to vaccine during pregnancy should be reported to the vaccine pregnancy registry (1-800-986-8999).

Contraindications to use of vaccine

Quadrivalent HPV vaccine is contraindicated for people with a history of immediate hypersensitivity to:

- yeast; or
- any vaccine component.

Precautions

- Quadrivalent HPV vaccine can be administered to females with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infections, with or without fever).
- Vaccination of people with moderate or severe acute illnesses should be deferred until after the illness improves (temporary precaution).

Adverse Reactions

Local injection-site reactions, including pain, swelling, erythema and pruritis, were the most common side effects reported. Systemic adverse events after vaccination were, on average, mild. Some of the systemic experiences that occurred more frequently in vaccine recipients included fever ≥100ºF (13.0% vs 11.2%), dizziness (4.0% vs 3.7%) and arthralgia (1.2% vs 0.9%).

Vaccine Efficacy

- Clinical trials in HPV-naïve women, 16 to 26 years of age, have demonstrated 100% efficacy in preventing cervical precancers caused by the targeted HPV types.
- HPV vaccine demonstrated 95-99% efficacy in preventing vulvar and vaginal precancers and genital warts caused by the targeted HPV types.

(Data do **not** indicate that the vaccine has any therapeutic effect on HPV infection or HPV-associated disease, including existing Pap test abnormalities or genital warts.)

Duration of Protection

The duration of vaccine protection is unclear. Current studies (with five-year follow-up) indicate that the vaccine is effective for at least five years. There is no evidence of waning immunity during that time period.

Vaccine Information Statements

An interim vaccine information statement (VIS) for HPV vaccine was issued on September 5, 2006, and is available at: www.immunize.org/vis. In the future, a *final* VIS will be re-published with a new date and a copy will be available at the above website.

Reporting of Adverse Events after Vaccination

It is important for all clinically significant adverse events to be reported to VAERS, even if a causal relationship to vaccination is uncertain. VAERS reporting forms and information are available electronically at: http://vaers.hhs.gov/ or by calling (800) 822-7967. Providers are encouraged to report electronically at: https://secure.vaers.org/VaersDataEntryintro.htm.

HPV and Cervical Cancer Screening

Cervical cancer screening recommendations have not changed for females who receive HPV vaccine.

- 30% of cervical cancers are caused by HPV types not prevented by the quadrivalent HPV vaccine
- Vaccinated females could subsequently be infected with non-vaccine HPV types
- Sexually active females could have been infected prior to vaccination
- Providers should educate women about the importance of cervical cancer screening and measures to reduce the risk of acquiring HPV infection.

References

ACIP Provisional Recommendations for the Use of Quadrivalent HPV Vaccine. Available at: http://www.cdc.gov/nip/recs/provisional_recs/hpv.pdf

A Human Papillomavirus Vaccine. The Medical Letter August 14/28, 2006;48:65-66.

Gardasil® Package Insert. Available at: http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf

Human Papillomavirus: HPV Information for Clinicians—CDC Brochure. Available from: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, GA. Available at: http://www.cdc.gov/std/hpv/hpv-clinicians-brochure.htm. [Accessed November 20, 2006.]

Vaccines for Children Program, Vaccine to Prevent Human Papillomavirus (HPV) Infection. Resolution No. 6/06-2. Adopted and Effective June 29, 2006. Available at: http://www.cdc.gov/nip/vfc/acip_resolutions/0606hpv.pdf